PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, January 9, 2008, 9:00 a.m., at the Department of Public Health, 250 Washington St., Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Ms. Caulton-Harris, Mr. Harold Cox, Dr. John Cunningham, Dr. Michèle David, Dr. Muriel Gillick, Mr. Paul J. Lanzikos, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Dr. Meredith Rosenthal, Dr. Michael Wong, Dr. Alan C. Woodward and Dr. Barry S. Zuckerman. Mr. Albert Sherman was absent. Also in attendance was Attorney Donna Levin, General Counsel, Department of Public Health.

Chairperson Auerbach announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance. He further announced that the meetings will now be scheduled for three hours instead of two hours. He said in part, "Since this Council has been meeting since April 2007, there has been a significant increase in the amount of activity that has been taken-up by the Public Health Council. As a result of that, we have found it necessary to lengthen the time period of our meetings from a two hour period to three….I think it is a credit to Members of the Council that they are an activist council, who are very interested in considering regulations that promote the health of the people of the Commonwealth. They are very interested in taking a serious and thoughtful look at the DoN process and applications that come before them, and they are also interested in being informed about important Public Health and health care related issues, and those things take time." He announced that on the agenda today would be (1) continuation of the discussion from last month on Limited Service Clinics; 2) consideration of three Determination of Need applications, one of which, the New England Sinai application is a continuation from last month's meeting. The third section of the agenda will be a presentation from the Betsy Lehman for Patient Safety on weight loss surgery.

REGULATION:

REQUEST FOR PROMULGATION OF AMENDMENTS TO 105 CMR 140.000 ET SEQ.: GOVERNING THE LICENSURE OF LIMITED SERVICES CLINICS (Continuation from last meeting of 12/12/2007:

Dr. Paul Dreyer, Director, Bureau of Health Care Safety and Quality, presented the Limited Services Clinics (LSCs) Regulations to the Council, accompanied by Dr. Lauren Smith, the Department's new physician. She will provide clinical as well as policy oversight for the Department.

Chair Auerbach introduced Dr. Smith and said, "We have asked Dr. Smith to join us at the table with Dr. Dreyer because a number of the questions that arose last month in the consideration of the regulation for Limited Service Clinics involves clinical consideration and a desire of the Council Members to be sure, as we proceed with consideration of

these types of clinics, that they would be operated with attention of quality of care for the patients, and that any potential problems were either minimized or prevented. We thought it important to have our senior clinical manager be actively a part of the process of looking at these regulations, and looking at the oversight that will be necessary for the clinics as they move ahead."

Dr. Dreyer said in part, "…We are proposing some changes to the language in response to the comments. We will be issuing some regulatory guidelines to qualify certain requirements with greater levels of specificity. We will be hiring a dedicated employee to oversee the process of licensure, with respect to initial approvals and on-site surveys. Dr. Smith will be overseeing clinical issues and we will be establishing an advisory committee to review clinical issues. Dr. Smith will be the Chair, and we will plan to report regularly to the Council on the status of Limited Service Clinic developments during the process." There were 13 issues that were raised at the last meeting and Dr. Dreyer addressed those as follows:

Conflict of Interest:

"The conflict of interest question arises in those situations where a Limited Service Clinic is located in retail space and there is an ownership relationship. A clear example is MinuteClinics being located in CVS pharmacies when MinuteClinic is owned by CVS Pharmacy. We have done the legal research and can find no generic problem with that practice. There is not to say that there couldn't be circumstances where problems arise, but those problems will be detected by monitoring a practice, and if those kinds of problems arise the legal process is available to us to take whatever appropriate action is necessary. At this point, I want to state that there is no problem legally with siting retail clinics in space where there is a common ownership situation."

Disrobing issue:

Disrobing and gowning – took the language out - there was too much confusion

Hand sanitizers:

Added new language requiring Limited Service Clinics to have hand sanitizers

Handicap Accessibility:

Clarified language as to how we assess handicap accessibility and what standards apply

Interpreter Services:

Added new language requiring at least telephonic interpreter services

Adjudicatory Hearing Decisions:

Retained Public Health Council involvement in decisions made by Hearing Officers

Tobacco Warning Signage:

Included a requirement that LSCs post disclaimer language with respect to sale of products in parent companies

Waiting Rooms:

Bureau of Health Safety and Quality will work with the Bureau of Communicable Disease Control to develop appropriate infection control guidelines for waiting room space in LSCs

Dr. Dreyer noted that staff felt the other five items are best addressed with references to the licensure process and then he explained the licensure process to the Council:

"First, we receive an application. There is a suitability review and Architectural plan review done simultaneously, then a pre-survey application review and then a DPH survey. A specialized DPH employee will oversee the process and the DPH Medical Director will oversee critical issues in the steps that follow. Suitability review is a process to determine if the applicant is responsible and suitable to be granted a license. It really has two components. One is a review of the applicant's compliance history, including whether they have been found in violation of any Medicare or Medicaid statutes. If someone has engaged in a practice that results in conflict of interest that results in some Medicare or Medicaid sanctions, then that would be uncovered during the suitability review process. We do a CORI check and there is also a financial component. We need to make sure that the applicant has the financial wherewithal to run what appears to be a successful operation. The clinic can not be licensed before suitability approval is granted. In the architectural plan review, plans must be submitted with the clinic applications. The project will be reviewed for compliance with the Physical Environment sector of the Licensure Clinic Regulations using the American Institute of Architects Guidelines for Design and Construction of Health Care facilities. The AIA has a section on small ambulatory care settings, and that is the section that, in general, applies. There are specific requirements of the Architectural Access Board, governing handicap accessibility, so the designated toilet room, the exterior route of access to the clinic from the handicap parking spaces, interior routes of access to the clinic. Those things all need to be vetted with respected ADA standards."

Dr. Dreyer continued explaining the licensure process: "The application will be submitted to the Department with a list of pre-identified diagnostic and treatment services. Then there will be a review of the clinical practice guidelines for the conditions that are on that list. The application has to come in with a list of treatments to be rendered and the Clinical Practice Guidelines that are relative to those treatments. We will look at that list of the clinical practice guidelines and refer any questions to the

Medical Director and to the Clinical Advisory Committee. The next step is on-site survey, and that basically has these steps: an entrance conference with the staff, review of the physical plant, and a review of documents. Staff is interviewed; there is an exit conference and a summary of any findings at the sites, and discussion of deficiencies if applicable. After the survey, if there are deficiencies, the report is sent to the clinic, which then will submit a plan of correction. The DPH will grant a license when the plan of correction is implemented."

Dr. Dreyer returned to the remaining five concerns of the Public Health Council:

Credentialing and Staff Qualification:

Regulations changed so it explicitly requires the qualifications of staff with children to be served. "DPH will review personnel files, policies and procedures and interview staff to determine staff qualifications and to verify current license, education, and experience. We will look at the clinic's methods to assess initial and ongoing staff competencies specific to the services provided and the patient population served," said Dr. Dreyer.

Evaluation of Quality:

There is a regulation that requires all clinics, including LSCs to establish quality assurance programs. During the pre-survey or on-site visit, DPH will look at the clinic's quality assurance plan. Dr. Dreyer stated, "For operational clinics, we look at the meetings of the Quality Assurance Committee, the governing, and any other relative committees that are obligated to oversee the quality assurance process. We look at such standards as whether the plan has an individual responsible for its implementation. We look at the quality assurance plan's mechanism to identify problems and the methodology for monitoring and evaluating quality of care. Essentially, this is a quality management process: Plan, Do, Check, and Act. That is the paradigm for quality assurance now in all health care facilities…"

Referral of Patients:

Added language which states: "including those circumstances in which telephone referral may be appropriate." Dr. Dreyer noted, "Staff will look at the clinic's protocols which may define whether the patient's needs are beyond the scope of services. We will look to see if the clinic has a referral list. We will look at their system for providing information to the patient. With respect to telephone contact, we will look at the clinic's ways of identifying whether a patient might require prompt attention and patients who might appear to need assistance with follow-up or anything else that might be relevant in telephone referrals. We will interview staff when they do orientation regarding referrals to verify that staff understands the requirements."

Toilet Facilities:

Added a clause which says that a LSCs' toilet facilities need to be reasonably proximate, based on the services provided by the clinic, to the Clinic's treatment area. Dr. Dreyer indicted, "This would be assessed during the site visit and staff will ask questions such as: Is there proximity with easy access to patients who require specimen collection? Are the specimens labeled? How are they transported to the clinic area? Where are they stored on-site after collection?"

In conclusion, Dr. Dreyer said, "It is certainly the case that the regulations we are reporting today are a better product with the Public Health Council's input. Again, let me reiterate that the Commissioner has committed to funding a new FTE to oversee the licensure effort, and the Department's Medical Director will actively participate in clinical review and will chair an Advisory Committee to address any ongoing clinical issues; and we look forward to briefing the Council on the status of the program at its convenience."

Chair Auerbach added, "…I would just reiterate that, in attempting to respond to the list of issues that people raised last time, what we found was, some of those issues lend themselves to regulatory language. Other issues, sometimes you just can't address those issues through regulatory language. It is just too detailed but they can be addressed by having dedicated staff scrutinize the applications, interview the applicants, do on-site visits, and withhold the granting of an application until the various components address the issues that you raised and that staff will be paying attention too. In addition to having a staff person who would carefully oversee that in great detail, we also thought that paying attention to the clinical issues in a new arena, with careful oversight by Dr. Smith and the Advisory Committee, would also help to address some of the other concerns which, again are very real concerns that we should pay attention to, but are not necessarily best addressed with regulatory language. That is the kind of thinking that is behind this multi-faceted approach of how best to address your issues."

Chair Auerbach moved for acceptance of the proposed regulations, along with the additional language added in Attachment 2. Dr. Muriel Gillick seconded the motion. Discussion followed.

Council Members had the following concerns or comments:

Dr. Zuckerman wanted clarification of how DPH was checking the credentials of LSC personnel; and he also wanted to raise the issue of the feasibility of an evaluation. Drs. Dreyer and Smith assured him that the credentials would be scrutinized by staff. Dr. Dreyer said that the data would be available for collection via the required electronic records.

Dean Cox questioned, "Are we making these regulations more onerous and complicated than they need to be?" He said in part, "…I believe that as a Council, we have a responsibility for thinking through policies that will improve health and public health for the public but I just want to be careful about the policies that we are actually recommending here, that they are things that we really need to be putting in place because what we put in place for this particular company will be applicable to anyone who wants to set-up a Limited Service model, irrespective of whether it is one of your hospital, whether it is some other public health entity. It doesn't matter; corporate, non-corporate, non-profit, for profit kind of things…"

Dr. Gillick noted in part, "…I think we have before us a set of regulations that assure us that we will have adequate supervision on quality in Limited Service Clinics…"

Dr. Wong noted that some things become standard due to accrediting institutions' standards like JCAHO: "…While some of these things (for example hand sanitizers at health facilities) never needed to be formally promulgated, there are sources that exist, that really kind of provide the pressure to get many of these institutions to meet certain standards…"

Dr. Wong further noted his concern about for profit organizations setting up clinics and duplicating services which already exist and wonders if instead we should be improving access to care in existing infrastructures.

Commissioner Auerbach, Chair said, "I would really emphasize that the regulations before you are not regulations that are retail establishment clinic operation regulations. The department specifically made a decision not to do that but instead wanted to create a set of regulations which allows clinical services to be provided in the non-traditional setting with only a limited number of clinical practices being offered with the thinking that this would be a model that would be of interest to a number of different entities, including retail but also hospitals and community health centers and so we tried to adapt these regulations so they would be useful in multiple different applications – not just one model."

Dr. Dreyer mentioned two very different kinds of potential models (folks who testified at the public hearings on LSCs) that showed interest in such clinics was Planned Parenthood and a large physician practice (hospital-affiliated) located in Western Massachusetts." Other possibilities mentioned were outreach worker drop-in centers and homeless shelters.

Dr. David, noted, "I actually left the last meeting with the mindset, on the point the Commissioner just made. This could actually be a way to recondition the emergency rooms -- to be able to say to a patient who calls you, why don't you drop-in at that place [LSC] instead of saying -- go to the emergency room, if you couldn't handle it over the phone…"

Dr. Woodward voiced his concerns: (1) He would like to see tighter language for tobacco signage; (2) Regarding referrals he said, "I think the language on follow-up is enhanced. I still have a concern where nurse practitioners in the State are supposed to function under the supervision of a physician. I think there should be a physician that is available by phone to the practitioners for when the patient doesn't fall on the algorithm, can be reached by phone and can provide help with referrals, help in integration….These practitioners are isolated. They are not providing the integrated health care delivery that we are trying to achieve. We know from multiple studies now that if patients receive health care where they have a primary care provider in an integrated delivery system that their continuity of care, their preventative care and their cost of care are all improved, are all better, and this is sort of a disintegrated business model…"

Dr. Gillick asked legal counsel: "It was my understanding that what we are asked to vote on is not whether we like the model that is being proposed or not, but whether these regulations would provide adequate assurance that the citizens of the commonwealth of Massachusetts would be protected in such clinics. Is that fair?" Donna Levin, General Counsel replied that they could vote either way – depending on their conscious.

Chair Auerbach added this amendment regarding the tobacco signage warnings: "I propose that we alter140.1001L so that the specific language is, "If the Limited Service Clinic is located in a retail location that sells tobacco products, it must post information regarding the dangers of tobacco usage, the message of which is determined by the DPH Tobacco Control Program. Is that a friendly amendment Dr. Gillick since you seconded, my motion?" "Yes – very good", replied, Dr. Gillick.

Discussion continued around the issue of making sure patients receive proper back-up care and whether there should be physician back up for the nurse practitioners. [Please see verbatim transcript for full discussion]. Chair Auerbach said, "My suggestion would be that we consider that a specific amendment on that particular requirement be voted on." Dr. Meredith Rosenthal, Council Member added, "I just wanted to jump in a little bit on the point that Dean Cox had initially raised which I think, while we are an activist Council and we all have very strong feelings about protecting the public health here, we need to be careful about using this very small regulatory arena as the place where we try to change the entire health care system. I think we all would like to see people in the Commonwealth having something that looks like a patient-centered medical home but, frankly, that doesn't exist and, with no disrespect to my clinical colleagues, we do have terrific care here in Massachusetts, relatively speaking, but there are a lot shortcomings, and we need to think about ways that we can address them in the short-run, and think about much larger sets of regulations having to do with the way Medicaid works, having to do with a lot of other things, whereby we can really address the fundamental problems. So, I too am nervous about burdening this piece of regulation with so much weight that, because of the other goals that I think we all share, that we basically tank this. With that said, I think that the only other question I wanted to pick-up on, does anyone know the extent to which clinics are JCAHO accredited in any instances?"

Dr. Dreyer answered, "I know that MinuteClinic is accredited by JCAHO in Minnesota. I don't know about any of the other potential retail clinics elsewhere, but I do believe there are forty clinics in Minnesota that are JCAHO accredited." Dr. Rosenthal noted as Dr. Wong said earlier that JCAHO may be an alternative mechanism for quality assurance or oversight to take into account. However she added, "One should not put too much weight on market forces, per se, but there are other oversight bodies that are not regulatory, but may have an influence."

Chair Auerbach noted, "There are clearly a number of issues that are making it challenging for patients to receive primary care within the Commonwealth and they have to do with physician shortages in certain areas, nurse shortages in certain areas, the lack of available practices, waiting lists, reimbursement practices and just a lot of challenges. I think that we should make a commitment as a Council, and I say it on behalf of the Department, we pledge to do this, that we revisit these issues on a regular basis and we look at systemic changes that are possible, being open to rethink what are the broader components of our political regulations on a number of different issues, including this. I think it would be a healthy thing for us to do. Thinking about ways of increasing access would be a healthy thing for us to do. I do want to say publicly. This is not the only day that we have the opportunity to talk on this. We have to be thinking, as a Council and as a Department, about creative ways to bring those issues forward in both regulatory and non-regulatory ways. We hear you saying, there are big problems that need to be addressed."

Council Member Paul Lanzikos stated, "…Once a referral is given to the consumer, it becomes the consumer's responsibility to follow-up. I have two referrals right now, sitting on my desk, from my primary care physician for physical therapy and podiatry. I haven't acted on them. It is my responsibility, not my primary care. I think when we are doing oversight; we should make sure we cover only what the provider is responsible for, not the behavior of the consumer."

Council Member Lucilia Prates Ramos added, "While I feel this regulation should not be onerous, we are setting a precedence here, and I am concerned about that…I understand about the access to care, the impact on emergency rooms, taking care of some of that overcrowding. I don't think it will take care of it, but alleviate some of it. I think we need to think about access to quality care, and I just want to put that out there to really think about; and in a response to what Paul Lanzikos said about consumer responsibility. I firmly agree with you. We all have responsibility. However, when we are dealing with elders, dealing with people with limited English proficiency, that plays out very differently and I worry about the follow-up. We have institutions where we have interdisciplinary teams under the same roof and care is very fragmented and I speak to that very personally, being a health advocate for both of my parents, first my father and now my mother. I see that fragmentation taking place daily if I do not make that call and I do not become that coordinator."

Chair Auerbach said, "I think that is one of those reminders about why we need to be thinking about systemic change and addressing the issues we are talking about in a broad and comprehensive way."

Chair Auerbach stated, "We have a motion on the floor that has been seconded, but we have a suggested amendment to that motion regarding clinical backup. General Counsel Donna Levin suggested language and Dr. Paul Dreyer suggested language. Dr. Woodward chose Dr. Dreyer's language and added the word physician before consultation. The language which is already in 105 CMR 140.1001, subsection D. Just add a comma after appropriate, and add language, "or in which LSC staff may obtain physician consultation on unclear cases." Dr. Dreyer read the language again for the record "Each Limited Services Clinic shall develop policies and procedures for referring patients whose needs exceed the clinic's services, including those circumstances in which a telephone referral may be appropriate, or in which LSC staff may obtain physician consultation on unclear cases."

Dr. Woodward made the motion to add further language as stated above by Dr. Dreyer to Limited Services Regulations. Council Member Lanzikos said for the record, "I agree with the thrust of the proposed amendment, though I actually will vote against it in that I don't think that this is the proper locus for that requirement. Nurse practitioners or the other practitioners have regulations that govern their own practice and, to my understanding, does require such consistent supervision, and I think that should be the governing regulation, and we should then get, in the clinic and the facilities-based regulations involved with professional contact that is otherwise covered through regulation." Dr. Woodward responded in part, "…It isn't required but it is available. We are saying here, where these practitioners are usually isolated, that it is beneficial for them to have that telephone access in an unusual circumstance where they need consultation."

After consideration, upon motion made and duly seconded it was voted: (Dr. Cunningham, Mr. Rivera, Dr. Rosenthal, Dr. Wong, Dr. Woodward and Dr. Zuckerman in favor; Mr. Auerbach, Mr. Cox, Dr. David, Dr. Gillick and Mr. Lanzikos opposed; and Ms. Caulton-Harris and Ms. Prates-Ramos abstaining; Mr. Sherman absent) to approve the **amendment to 105 CMR 140.101. (D)** As follows:

"Each Limited Services Clinic shall develop policies and procedures for referring patients, whose needs exceed the clinic's services, including those circumstances in which a telephone referral may be appropriate, or in which LSC staff may obtain physician consultation on unclear cases".

After consideration, upon motion made and duly seconded, it was voted: (Chair Auerbach, Mr. Cox, Mr. Cunningham, Dr. David, Dr. Gillick, Mr. Lanzikos, Dr. Rosenthal, and Dr. Zuckerman in favor; Ms. Caulton-Harris, Ms. Prates Ramos, Mr. Rivera, Dr. Wong and Dr. Woodward abstaining; Mr. Sherman absent) to approve **Promulgation of Amendments to 105 CMR 140.000 et seq: Governing the Licensure of Limited Services Clinics with an added amendment to 105 CMR 140.1001(L)**

relative to LSCs having tobacco warning signs in retail establishments; that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy is attached and made a part of the record as **Exhibit No. 14, 896**. The amendment is below:

"If the Limited Service Clinic is located in a retail location that sells tobacco products, it must post information regarding the dangers of tobacco usage, the message of which is determined by the DPH Tobacco Control Program."

DETERMINATION OF NEED PROGRAM:

COMPLIANCE MEMORANDA:

PREVIOUSLY APPROVED PROJECT OF NEW ENGLAND SINAI HOSPITAL – Request for Transfer of Site of 19 hospital beds licensed to provide chronic disease services from New England Sinai Hospital, Stoughton to a satellite at New England Rehabilitation Hospital, Woburn (continued from last meeting of 12/12/207):

Chair Auerbach made introductory remarks and apologized that the Council could not complete the process at the last meeting. He said in part, "We do believe that this is a matter which deserves our full attention and not a rush review; and, therefore, we felt like it was very important to give it the attention that it deserves." He noted that the Council has reviewed the application, including a transcript of the last meeting. He further said that speakers will have three minutes each to address the Council so that they can get to the question and answer period.

Ms. Joan Gorga, Director, Determination of Need Program, presented the request by New England Sinai Hospital (Sinai) to the Council. She noted in part, "…Sinai wants to transfer the site of 19 hospital beds from the hospital's main campus in Stoughton to the satellite facility in Woburn…The Department, within the 20 day period of the filing of the transfer, received comments objecting to the proposed transfer. For the reasons stated below, staff is recommending denial of the transfer. The regulations concerning transfer of site under the Determination of Need Program states that transfer of site must not substantially change the population served, defined as the population residing in the cities and towns whose patients rank numerically from highest to lowest contribute 75% of the facility's discharges. Sinai seeks to transfer beds to Woburn. The hospital, however, does not presently include Woburn on its list for 75% of patients ranked numerically. Therefore, serving Woburn would change the population and Sinai does not meet the test for substantial change of the population served."

Ms. Gorga noted that the second part of the regulation on transfer of site discusses access and Dr. Dreyer spoke on that. He said, "The question is – What does access mean? And the one thing we can be clear on is – it does not mean convenience. If it meant convenience, then any movement to some town would always increase access. So, that can't be want it means. Whatever it means, it is something other than access."

Ms. Gorga noted for the record, "On December 29th, President Bush signed 2499, the Medicare Medicaid Extension Act of 2007. Long Term Care hospitals, including Sinai hold Medicare certification. Section 114 of this act amends the definition of long term care hospital sites, establishing a two year moratorium on the increase of long term care hospitals and satellite facilities….The request by Sinai would not be permitted under this moratorium…" Ms. Gorga noted that in the event, the Council decided to approve the application, the decision can be made retroactive to the date of the last Public Health Council Meeting of December 12, 2007, according to the Department's General Counsel.

Lawrence S. Hotes, M.D., Chief Medical Officer, New England Sinai Hospital, addressed the Council. He said that approval would be in the best interest of the patients and that the other long term care hospitals are at full capacity at 75% occupancy because private rooms are not available in all of the facilities. Dr. Hotes said further, "We also note that Lahey Clinic has described to you the need for significant expertise and competency that the LTCH can provide. We have an interest in providing that care at our former Waltham location. These beds were located at the Waltham location, and we had a strong relationship with Lahey. That unit had to close four years ago when Waltham Hospital closed. As a result, they ended up developing a relationship with Kindred in Peabody, but that relationship ended….The Winchester Hospital and Hallmark Health Care have publicly expressed the need for the beds. It is clearly a concern. In conclusion, the transfer we are requesting has no cost. The beds already exist. In fact, in Waltham, the beds would provide access for the elderly and indigent and they would only need to travel 15 miles every day not 25 miles to see a loved one."

Attorney M. Daria Liewenhous of Mintz, Levin, Cohn, Ferris, Glousky and Popeo, P.C., representing Kindred Hospital North Shore and Kindred Hospital Waltham noted in part, "…This request should not be approved based on the Determination of Need Regulations. The staff summary clearly sets forth the reasons why this request should be denied. Denial is the only result based on verifiable data. Staff appropriately rejected, or found irrelevant, information Sinai presented to try to salvage this request, which was inaccurate. Staff did not acknowledge that 340 patients won't get care on page 5 of the staff summary. Staff says that current providers can serve those patients if in fact those patients exist…Sinai simply wants to move out of its service area and squarely into the middle of the service area of the Kindred Hospitals, which already serve Lahey, Winchester and Hallmark Hospitals. The Kindred Hospitals are able to take all clinically appropriate patients as soon as they are ready for discharge. Convenience, proximity are not criteria for approval of a transfer of site request….Approval will harm the two Kindred Hospitals, the very harm that the regulations seek to avoid. The regulations should be able to safeguard the integrity of the health care system. Sinai's ability to enter into contractual arrangements with Lahey or others in connection with the proposed satellite has no place evaluating this request. To be very clear, the Kindred facilities, like any other LTCH, and Sinai provide the same types of care to the same patient population…The transfer of site request does not meet the regulatory requirements. We respectfully urge the Council to accept the staff's recommendation."

Mr. David Storto, President of Partners Continuing Care, and representing Shaughnessy Kaplan emphasized a couple of points:

"Staff's interpretation and advocation of the standard in this situation is clear and unequivocal. There is simply no need that has been demonstrated to transfer these 19 beds to Woburn."

Regarding the applicant's remarks on patient population (i.e., ventilator-dependent patients and the need for private rooms) he said, "Shaughnessy-Kaplan, like other LTCH in the marketplace, like Kindred, like Youville have a ventilator program. Shaughnessy-Kaplan's have been in existence for years. It has excellent clinical outcomes, performs extremely well in the national benchmarks, is tracked by the National Association of Long Term Care Hospitals, discharging more patients back home to the community than the national standard, and weaning more patients than the national standard. Shaughnessy works closely with all its referring hospitals, including the Lahey Clinic, in relation to their patients and maintaining continuity of care. In the case of emergency, there is the availability of acute services adjacent at the Salem Hospital until a patient can be returned to their referring hospital of origin. Relative to the issue of the need for private rooms, in the case of Shaughnessy-Kaplan…the average daily census, the average occupancy is roughly 70% and we see no difficulty increasing that to an average of 85% in blocking semi-private rooms where necessary to deal with infection control issues, as well as other medical issues; and, by the way, Shaughnessy-Kaplan also accepts Medicaid patients, and Medicaid pending patients."

In closing, Mr. Storto said, "…Aside from the fact that there is no demonstrated need in this situation, this marketplace is actually very over-bedded relative to other parts of the country with long term acute care beds and, anecdotally, most of the providers in this area are struggling, in fact, because it is difficult to manage the overhead cost with the lack of current and anticipated future volume for this type of service. The legislation that Ms. Gorga referred to, that was passed at the federal level, was in recognition of this. It imposes a moratorium on the establishment of new programs and satellite programs on the increase of beds. So, simply, to approve this application would be bad policy."

Mel Hecht, M.D., Chief Medical Officer, Youville Hospital, addressed the Council. He stated, "…I have been the CMO for 16 years and during that period of time, we have seen the delivery and increasing complexity of patients and the implementation of clinical relationships with most of the major academic centers throughout the Boston Metropolitan area. Youville operates a thirty bed ventilator program with critical care and pulmonary care…Imperative data of our programs over national data also show that our rate and discharge to home rate at or above the national averages…."

He said further, "For the past five years, Youville has increased its capacity and relationships with tertiary hospitals, including Lahey Clinic, to manage patients with heart, lung, liver and bone marrow transplants. We provide chemotherapy and a full spectrum of pulmonary services. Our clinical specialists come from wholly academic centers and referrals come from such hospitals as Beth Israel, Mount Auburn Hospital

and Cambridge Hospital….In the year 2006, we had one ventilator admission from Lahey Clinic. In the fiscal year 2007, we had 16 ventilator patients. Total admissions from Lahey Clinic went from 16 in 2006 to 56 in 2007….We support the staff recommendation to deny this transfer application."

For the record, Council Member Lucilia Prates Ramos noted that she recused herself from voting on this New England Sinai Hospital application. Ms. Helen Caulton-Harris moved to approve staff recommendation. After consideration, upon motion made and duly seconded, it was voted (unanimously) [Ms. Prates Ramos recused herself] to deny **Previously Approved Project of New England Sinai Hospital's Request for Transfer of Site of 19 Hospital beds** Licensed to Provide Chronic Disease Services from New England Sinai Hospital, Stoughton to a satellite facility at New England Rehabilitation Hospital, Woburn, based on staff findings. A copy of the staff memorandum to the Council is attached to the December 12, 2007 minutes as **Exhibit No. 14, 895.**

Staff's findings indicated the following:

New England Sinai's failure to satisfy 105 CMR 100.720 (I) (1) that the transfer of site will not change the population served. Staff also finds that the proposed transfer of site fails to satisfy 105 CMR 100.720 (I) (2) because it will not significantly increase access at the proposed new site.

PREVIOUSLY APPROVED PROJECT No. 4-3A38 OF SOUTH SHORE HOSPITAL – REQUEST FOR A SIGNIFICANT CHANGE TO INCREASE THE PROJECT'S MAXIMUM CAPITAL EXPENDITURE FOR A NEONATAL INTENSIVE CARE UNIT (NICU):

Ms. Joan Gorga, Director, Determination of Need Program, presented the South Shore Hospital project to the Council. She noted, "South Shore Hospital is before you this morning for a significant change to its neonatal intensive care unit (NICU). In January of 2003 a Determination of Need was issued for establishment of a 10-bed Neonatal Intensive Care Unit (NICU) located in 787 GSF of renovated space. In 2007, the hospital requested an increase in renovation space of 1,825 GSF, a minor change and it was approved on June 13, 2007 to allow for better clinical and process flows. The amendment for a significant change was filed on October 27, 2007 to increase the inflation adjusted MCE from $210,038 (October 2007 dollars) to $674,000 (October 2007 dollars), an inflation-adjusted increase of $463,962 (October 2007 dollars). This allocation is a result of a net effect of $343,987 increase in renovation costs including architectural fees and an $119,975 increase in major movable costs."

Ms. Gorga noted at the meeting and in the staff memorandum, "Construction costs increased dramatically after Hurricane Katrina and projects at the hospital have been subject to a dramatic increase in construction costs particularly in the costs of metals. Equipment costs have increased for two reasons; first, the standards for care have changed in the five years since the unit was approved. For example, controlled environment beds and the use of nitrous oxide for neonatal respiratory distresses and the

use of high frequency ventilation have been proven to improve outcomes and have become the standard of care. Second, additional equipment had to be procured in order to meet the Department's recently revised Perinatal Regulations."

Staff's memorandum explained, "Staff has reviewed the community initiatives offered by the South Shore Hospital in conjunction with the NICU and is recommending an additional community initiative of $69,594 dollars to be approved based on the increase in MCE that is subject to this change. The applicant generously offered an original community initiative which was higher than usual. Staff will recommend that the additional community initiatives be approved for the increase, in proportion to the original contribution. The initiatives are based on the difference between the inflation adjustment increase and the new request. The program is to be funded in a time period that the contributions are being negotiated by the holder and the Office of Healthy Communities. Staff is recommending that the request for significant change be approved, and South Shore Hospital is here today to answer any questions."

Questions followed by the Council. Some of questions were: Dr. John Cunningham, said, "This is meant to be a friendly comment on the community initiatives. Couldn't we just make it $69,500 and keep it similar in magnitude to all the other figures?" Ms. Gorga replied, "Yes." Council Member Harold Cox asked for clarification on the total amount of the community initiative contribution. Ms. Gorga clarified that it is an additional $69,000 dollars, beyond the original $22,000 dollars. And further that the figure is based on the difference between inflation adjustment and the new requested MCE.

Council Member Dr. Alan Woodward made the motion for approval of staff recommendation. After consideration, upon motion made and duly seconded, it was voted (unanimously) [Dr. Barry Zuckerman recused himself from voting] to approve the Request by **Previously Approved Project No. 4-3A38 of South Shore Hospital** for a Significant Change to Increase the Project's Maximum Capital Expenditure for a Neonatal Intensive Care Unit (NICU) based on staff findings. This amendment is subject to the following conditions:

1. The approved GSF for this project shall be 1,950 GSF for renovation.

2. The holder shall provide $69,594 (October 2007 dollars) in additional community initiatives for programs and the time period is to be negotiated between the holder and the Department's Office of Healthy Communities.

3. All other conditions attached to the original and amended approval of this project shall remain in effect.

PREVIOUSLY APPROVED PROJECT No. 4-3B18 OF BOSTON MEDICALCENTER – REQUEST FOR A SIGNIFICANT CHANGE TO INCREASE THE PROJECT'S MAXIMUM EXPENDITURE AND GROSS SQUARE FOOTAGE FOR A CYBERKNIFE:

Ms. Joan Gorga, Director, Determination of Need Program, presented the request for a CyberKnife by Boston Medical Center. Ms. Gorga said in part, "Staff is before you this morning with significant changes to the CyberKnife stereotactic radiosurgery system approved in February 2007. The hospital is requesting an increase in renovation space and in the maximum capital expenditure with spatial allocation and construction requirements between a dimensional linear accelerator and a CyberKnife. The increase in the square footage from the original approved is 1,436 GSF to 2,048 GSF and is necessary to allow for increased shielding and mechanical cooling equipment specific to the CyberKnife. The inflation-adjusted increase of $1,024,109 (September 2007 dollars) requested by the holder is the net effect of a $1,593,273 increase in construction costs and a $569,164 decrease in major movable costs.…"

Staff's memorandum to the Council further explains the community initiatives: "The community initiatives originally offered by the applicant and approved for the Boston Medical Center CyberKnife, Project No. 4-3B18, as part of the Notice of Determination of Need, were $230,000 (September 2006 dollars) to be expended over a five-year period to fund the development or expansion of programs to address specific healthcare needs and issues identified by Boston HealthNet community health centers in Mattapan and South Boston. Staff recommends that additional community initiatives be approved for the increase in MCE that is the subject of this significant change. Initiatives in proportion to the original contribution of the applicant and based on the difference between the inflation-adjusted MCE of $4,845,891(September 2007 dollars) and the new requested MCE of $5,870,000 (September 2007 dollars) would be $51,205 (September 2007 dollars). Staff will recommend inclusion of a condition recommending that the holder provide additional community initiatives of $51,205 (September 2007 dollars). The programs to be funded with the additional funds for community initiatives and the time period of the contribution will be negotiated by the holder and the Office of Healthy Communities."

The maximum capital expenditure is itemized as follows:

Construction Costs:

Construction Contract	$2,120,000
Major Movable Equipment	3,750,000
Total Construction Costs:	$5,870,000

Dr. Alan Woodward made the motion for approval. After consideration, upon motion made and duly seconded, it was voted unanimously [Drs. Michele David and Barry Zuckerman recused themselves] to approve the Request by **Previously Approved Project No. 4-3B18 of Boston Medical Center for a Significant Change** to Increase the Maximum Capital Expenditure and Gross Square Footage for A CyberKnife. This amendment is subject to the following conditions:

1. The approved GSF for this project shall be 2,048 GSF for renovation.

2. The holder shall provide $51,205 (October 2007 dollars) in additional community initiatives for programs and the time period is to be negotiated between the holder and the Department's Office of Healthy Communities.

3. All other conditions attached to the original and amended approval of this project shall remain in effect.

PRESENTATION: "BETSY LEHMAN CENTER FOR PATIENT SAFETY EXPERT PANEL 2007 UPDATE – WEIGHT LOSS SURGERY BEST PRACTICES TO PROTECT PATIENT SAFETY", By Nancy Ridley, Director, Betsy Lehman Center for Patient Safety and George L. Blackburn, M.D., PH.D., Expert Panel Chair, Beth Israel Deaconess Medical Center:

Chair Auerbach noted in part, "…The Betsy Lehman Center, under Nancy Ridley's expert leadership, was groundbreaking in terms of its examination of the appropriate recommendations regarding weight loss surgery a number of years ago, and your report was incredibly useful and widely read and accepted…And then with the terrific leadership of Dr. Blackburn, we were able to revisit and review the experience over the last couple of years and we are now to hear the exciting and interesting observations, understand the prevalence of this type of surgery, and look at the recommendations."

Ms. Nancy Ridley, Director, Betsy Lehman Center for Patient Safety, "I am going to be very brief because all of the credit for the success both in 2004, as well as in 2007, goes to the village that put together the report. There were 35 people on the expert panel that did the revision during 2007, and I know there were at least a hundred individuals who were actively involved in one or more of the eleven work groups. The rationale for us being here today and increasing our over one hundred evidence-based recommendations that we put forth in 2004 is because literature, science and technology changes, and the information that we have, we determined through our annual revisits of the work, is that significant changes had occurred and that the literature was sufficient to improve and increase, and enhance, in the name of patient safety. I might emphasize, this wasn't solely looking at efficacy for the procedure, but was really the safety of that procedure and the importance of being sure that these safe practices were carried through."

Ms. Ridley continued, "In April, we started the reconvening of the process and we completed it in August, and I want to make it really clear that I have never had the opportunity, actually until, I guess, recently with our infections work, of working with such a committed group or village, as I like to call them, of individuals, who were so committed, and it is not just physicians and surgeons, and I know Dr. Blackburn will attest to that. It is also the entire multi-disciplinary team that works with patients and with consumers on issues of obesity and weight loss."

"In terms of the explosive growth", said Ms. Ridley, "both nationally and in Massachusetts of weight loss surgery procedures, the actual performance of them has been phenomenal over the last ten years, and this is what actually prompted the Commissioner at the time to want to take a look at patient safety issues because we were starting to see as the number of procedures increased, as Dr. Dreyer knows, we were starting to see serious incidents being reported to the Department. We wanted to look behind those incidents and see if there was a need for us to take some type of an action; and, in Massachusetts itself, the numbers rose dramatically and have continued to rise."

Dr. George L. Blackburn, M.D., Expert Panel Chair, and on faculty of Beth Israel Deaconess Medical Center, addressed the Council next. He said in part (see verbatim transcript for full text of his remarks), "I think I will be able to show you that we have achieved all the goals that are sought for best practices….I want to draw attention to Dr. Alan Harvey, Chair Emeritus, who insisted we get buy-in from across the State so that we had representation of facilities that provided over 80% of all the procedures done in Massachusetts. There were nurses, social workers, consumers, people from the state legislature, so that we got a broad input of what exactly would be the guidelines and what would be the needed and required technology….It turned out that these teams working within the facilities were the cornerstone of what we needed to do."

Some Excerpts from Dr. Blackburn's slide presentation:

Rationale for Weight Loss Surgery (WLS) Expert Panel

- The original Lehman Center report, developed in 2004, informed best practice standards at home and abroad
- Since that time, the literature on WLS has expanded rapidly
- New procedures have been developed and new patient safety issues have been raised
- In April 2007, the Lehman Center convened a 35-member Expert Panel to update evidence-based recommendations published by Obesity Research in 2005

2007 WLS Expert Panel Update: Key Points

- Growing number of surgical options available
- Laparoscopy has displaced open surgery as predominant approach
- WLS accreditation/credentialing programs established within past 3 years
- WLS patients have a higher prevalence of mental health disorders, with preliminary evidence indicating substance abuse problems
- ˜4% of U.S. children suffer from extreme obesity
- Advances in anesthesiology allow for more precise dosing of muscle relaxants and novel applications of anesthetic agents
- New national credentialing standards in perioperative nursing
- New patient transport and lift technologies can reduce healthcare workplace injuries
- Optimal treatment requires greater collaboration between members of a multidisciplinary care team
- 99% of patients eligible for WLS do not receive it
- The need to accommodate growing numbers of severely obese patients will require wide-ranging changes in new and existing healthcare facilities
- Centers for Medicare and Medicaid Services and other payers now only reimburse procedures performed at accredited weight loss surgery centers

<u>Survival Advantage with WLS and Other Statistics</u>

- Swedish Obese subjects study: 31.6% reduction in adjusted overall mortality rate in surgical groups compared with conventionally-treated controls
- A collaborative research project in Utah: 40% mortality reduction in gastric bypass patients compared with the same number of age-,gender-, and BMI-matched controls
- A case control study: statistically significant difference in survival in favor of the surgically-treated group
- Social Security Death Index and office records: a 50% to 80% mortality reduction benefit with surgical intervention [Conclusion: Recent studies indicate that WLS confers a survival advantage on patients who undergo it compared with

community controls]

- The inpatient death rate in the Commonwealth is .07 percent. The lowest mortality rate in the hospital for general surgical procedures of any kind. Dr. Blackburn said, "We can only conclude that what we have done is provide the latest, most effective and safest procedure for treatment of these patients who are suffering from severe conditions

- The Expert Panel has 11 Task Forces, the latest being the latest technique, endoscopic procedures

- The procedure is a disease prevention method in that it reduces diabetes, heart disease, certain cancers, hypertension and dependence on medication

<u>WLS Associated with Increased Non-Disease Mortality</u>

- WLS patients had 58% greater death rates from non-disease causes (such as accidents and suicide) than the control group

- Previous studies suggest a link between WLS and an increase in drug and alcohol abuse and other risk-taking behaviors

- Substantial number of severely obese persons have unrecognized presurgical mood disorders or post-traumatic stress disorder or have been victims of childhood sexual abuse

- Further research is warranted to explore:

    - Optimal approach to evaluating candidates
    - Need for pre-op psychological evaluation and psychiatric treatment before surgery
    - Aggressive follow-up after surgery

In conclusion, Dr. Blackburn stated, "The surgical death rate is significantly less in controlled Swedish and U.S. studies…I would then conclude with the fact that our mission has been accomplished – that it was a hundred volunteers who were expert, who did the work and presented it. Over one thousand implementations have taken place since 2004…"

Ms. Nancy Ridley, added, "…It has been extremely rewarding to be able to characterize such a low adverse morbidity rate associated with a particular surgical procedure. I think it is also extremely important to point out that one of the things that happened in 2004 was, there was no accreditation, no credentialing program, nothing out there, and part of the problem with the explosive growth in other parts of the country was that it was being looked at as being an entrepreneurial or a potential source of money-making, and developing evidence-based standards when we did, I know served as the source for the

National Credentialing and Accreditation Programs, and the fact that AHRQ, the Agency for Health Research and Quality, adopted these evidence-based guidelines in their National Guidelines Clearinghouse is important."

Ms. Ridley noted further, "…These practices will not only be sent out to all of the facilities in Massachusetts, but one of the other things we found very successful was, the Commissioner will be sending out a copy of these to his counterparts in all other states, as well. We did this in the first round, and we will do this again with this round so that we can share our findings in our organizations with other states that go through some of the same challenges that we do. Payers and Managed care plans have adopted these as the Standards of Practice, and we are very pleased that we have had some very good managed care plans and payers, both government (CMS and Medicaid) as well as private sector and non-profit, serve as part of our process so that it provides a lot of rationality to making decisions for access, when the access is important for a particular individual."

A brief discussion followed by the Council Members. Dr. Alan Woodward said in part, "I think this is extraordinary, wonderful. I see clearly demonstrated improvement in the treatment of a preventable disease….Maybe we can hear more about it at another Public Health Council meeting." Chair Auerbach inquired about weight loss surgical candidates having a higher prevalence of mental illness and substance abuse behaviors pre and post surgery. Dr. Blackburn responded by noting that there is a detailed Utah study that addresses the question and said in part, "We need to have empathy and recognition of people with severe obesity…it is not because of their eating habits but due to their metabolisms…We have fortunately intense research activity in the Commonwealth, trying to understand, in a sense, a treatment….Another thing that has been found is the stigma, through genetics, through evolution, these people are particularly fragile." Dr. Blackburn mentioned a study of two control groups, those who received the surgery and those who were to receive it and the study showed a remarkable increase in suicidality. Dr. Blackburn further noted that as a result of the Expert panel they have instituted a multi-disciplinary structured program for candidates of the surgery. He noted, "The statistics in the commonwealth are about five percent of the people screened in the survey were found to be so psychologically impaired that they are not found to be safe candidates for the surgery. Another 25% had to delay the surgery until they do get a provider to work with this and agree that they are eligible and then there is a five year follow-up after the surgery including psychological evaluation."

Ms. Nancy Ridley added, "I think it is important to point out the pre and post operative period is really for a lifetime in the case of individuals who are obese and who may or may not be eligible for the surgery. It doesn't begin with the surgical procedure and it doesn't end with the surgical procedure. It is extremely important for us to keep a focus on the lifetime work that is needed and attention that is needed to this issue."

In regards to Chair Auerbach's question on high prevalence of substance abuse and mental illness, Ms. Ridley noted, "We are going to be crafting jointly with Michael Botticelli, Director, Bureau of Substance Abuse Services, who was aware of these findings from his own sources, a joint letter, specifically on asking providers and

practitioners to be cognizant of some of these newer findings about suicidal and addictive behaviors that seem to be occurring. We are going to be sending out a focused request to bring attention to that."

No Vote/Information Only

Chair Auerbach noted Council Member Albert Sherman's absence. "I just wanted to propose on behalf of the entire Council we extend our best wishes, hopes and prayers to Albie and send him an official get well soon recognition. I am sure he will appreciate hearing from all of his fellow Council Members, and we will keep you posted on his health status and let you know how to reach him yourself."

The meeting adjourned at 11:30 a.m.

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John Auerbach, Chair

LMH